Remarks

This Response is in response to the Office Action dated **November 14, 2007.**

Rejections

35 U.S.C. §

Cox et al. in view of Garrison et al. and further in view of Erbel et al.

Claims 1, 2, 4, 5, 7-10, 15, 26-28, 34 and 35 are rejected under 35 U.S.C. §103(a) as being unpatentable over Cox et al. (USPN 6,652,579) in view of Garrison et al. (USPN 6,520,984) and further in view of Erbel et al. (US 2004/0116998).

Applicant traverses the rejection.

Claim 1 is directed to a medical device having, among other features, a first serpentine band and a second serpentine band adjacent thereto, each serpentine band formed of interconnected struts and having a distal end and a proximal end, each strut extending between a peak at the distal end of the serpentine band and a trough at the proximal end of the serpentine band, at least one of the struts being a special strut and at least one cover on at least one region of the medical device, a plurality of the radiopaque markers marking the proximal end of the at least one region and a plurality of the radiopaque markers marking the distal end of the at least one region.

Marking either end of the covered region of the stent allows for proper placement of the covered region of the stent for at an aneurysm, for example, to prevent leakage of blood, the positioning of which can otherwise be challenging. See paragraph 0005.

The special strut 104a, recited in independent claim 1, is located within a single serpentine band 108 and extends from a peak at the distal end of the serpentine band to a trough

at the proximal end of the serpentine band.

Applicant agrees with the assertion made in the Final Office Action while the primary reference, Cox et al. failed to disclose such a strut. Combining the covering element disclosed by Erbel et al. with the stent structure disclosed by Cox et al. failed to render claim 1 obvious because the stent structure of Cox et al. is different.

Cox et al. disclose a stent having high mass connecting links 54 that are radiopaque (see FIG. 6, for example) that actually connect one serpentine band 30 to an adjacent serpentine band 30 and which extend from a trough of serpentine band 30 to a peak of an adjacent serpentine band 30.

Connectors are not struts.

The examiner has agreed with Applicant that "Cox does not disclose that the special strut extends from a peak at the distal end of the serpentine band to a trough at the proximal end of the serpentine band." However, it is asserted that "Garrison discloses a stent (37, Fig 1) with a radiopaque marker (42) extending from a peak at the distal end of the serpentine band to a trough at the proximal end of the serpentine band Garrison also discloses a stent (72, Fig 2) with a radiopaque marker (79) extending from a peak/trough of one serpentine band to a peak/trough of another serpentine band, just as is disclosed by Cox." Office Action, page 3, paragraphs 5 and 6.

With this, Applicant disagrees.

Garrison et al. disclose a stent-graft assembly including "…a stent and a graft in the form of a polymeric sleeve extending over at least a portion of the graft….First and second expandable security rings are disposed over the first and second ends of the graft and serve to secure the first and second ends of the graft to the stent to prevent inadvertent displacement of the

graft with respect to the stent during deployment of the stent graft into the vessel of the patient." Abstract.

Garrison et al. fail to disclose radiopaque markers that are located between a peak and a trough of a single serpentine band of a stent.

Garrison et al. do disclose that radiopaque markers can be carried by the stent or by at least one of the security rings and the markers project in a direction so that a depression is formed in the graft to help ensure that the graft and ring will not become displaced with respect to the stent. See claim 1. However, Garrison et al. fail to disclose or illustrate anywhere on the stent a radiopaque marker would be disposed.

The security rings shown in FIGS. 1 and 2 include radiopaque markers. The security ring shown in FIG. 1 of Garrison et al. has a structure which is quite different from the circular belts 21 of the stent shown in FIG. 1.

In FIG. 2, the security rings have a similar structure to the circular belts 21 of the stent shown in FIGS. 1-3 of Garrison et al. In this embodiment, the radiopaque marker is located between two adjacent circular belts in the security ring, and interconnects the two circular belts. Consequently, without employing the benefit of impermissible hindsight, using Applicant's own invention, one of skill in the art would be lead to employ the markers between the circular belts 21 of the stent, but one would not be lead to place them in a single circular belt 21 between a peak and a trough, i.e. in the strut, as recited in claim 1.

Neither of these references discloses a cover of the type recited in claim 1. See page 4, item no. 8 of the Final Office Action.

It is asserted, however, that:

Erbel et al. disclose an endovascular prosthesis (Fig. 3) or stent 20) comprising at

> least one cover (25) disposed about at least one section of interconnected serpentine segments, marked at the distal end and proximal end by a plurality of radiopaque markers (35). Erbel teaches that the "use of such radiopaque markers facilitates correct placement" of the stent (Para 90)....
>
> It would have been obvious to one of ordinary skill in the art to incorporate a cover disposed about the stent in the area of radiopaque markers. Using a cover on the stent enhances the properties of the stent to cause thrombosis at the site of the aneurysm or tear while at the same time allowing blood to flow through the stent and the vasculature. Using radiopaque markers at the edge of the cover facilitates correct placement of the cover at the site of the aneurysm or tear in the body lumen. Erbel provides the motivation. The inventions are analogous with each other and with the instant invention therefore a combination is proper.

Final Office Action, pages 4-5, paragraphs 8-10.

Erbel et al. disclose an endovascular prosthesis having a porous section and a non-porous section. See Abstract. Radiopaque markers can be disposed at the distal edge of the tubular wall of the prosthesis and at points along the distal edge of the non-porous section. See FIG. 3 and paragraph 0090. Erbel et al. fail to disclose radiopaque markers located on the strut of a serpentine band as recited in Applicant's independent claim 1.

Therefore, this combination of references, without the benefit of hindsight, fails to lead one of skill in the art to a special strut located between a peak and a trough of a serpentine band, i.e. on the strut, of a stent.

Claims 2, 4, 5, 7-10, 15, 34 and 35 depend from claim 1 and are not obvious over this combination for at least the reasons that claim 1 is not obvious over this combination.

Independent claim 26 recites a stent having, among other features, special struts extending from the peak of the serpentine band to the trough of the serpentine band and having a radiopaque marker therebetween.

Claim 26 as well as claims 27 and 28, which depend therefrom, are not obvious over this combination for at least the reasons that claim 1 is not obvious over this combination.

Applicant respectfully requests withdrawal of the rejection of Claims 1, 2, 4, 5, 7-10, 15, 26-28, 34 and 35 under 35 U.S.C. §103(a) as being unpatentable over Cox et al. (USPN 6,652,579) in view of Garrison et al. (USPN 6,520,984) and further in view of Erbel et al. (US 2004/0116998).

Wolinksy in view of Burgermeister and further in view of Erbel et al.

Claims 1, 2, 4, 5, 7-10, 15, 26-28, 34 and 35 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Wolinsky (USPN 6,730,116) in view of Burgermeister (USPN 6,790,227) and further in view of Erbel et al. (USpub 200410116998).

Applicants traverse the rejection.

Claim 1 is directed to a medical device having, among other features, a first serpentine band and a second serpentine band adjacent thereto, each serpentine band formed of interconnected struts and having a distal end and a proximal end, each strut extending between a peak at the distal end of the serpentine band and a trough at the proximal end of the serpentine band, at least one of the struts being a special strut.

Each special strut has a first side with a first region of first curvature and a second side with a second region of second curvature, the first region opposite the second region, the first region curving in a direction opposite to the second region relative and a radiopaque marker between the first and second regions, and a cover on at least one region of the medical device.

The first serpentine band is connected to the second serpentine band by a connector which extends from one of the ends of the first serpentine band to one of the ends of the second serpentine band.

In the Office Action, Burgermeister has been combined with Wolinsky et al.

because "Wolinsky et al. does not disclose that the serpentine bands are connected by a connector, which extends from one of the ends of the first band to one of the ends of the second band....Burgermeister discloses a stent with serpentine bands having peaks and troughs with each band connected to the adjacent band by connectors....Burgermeister states that this connector is advantageous because the overall length of the stent is maintained during expansion." See Office Action, page 6, paragraphs 13 and 14.

Applicants disagree and submit that in fact, Burgermeister would not be combined with Wolinsky et al. for this purpose because in the Background of the Invention, Wolinsky et al. disclose that Globerman, U.S. Patent No. 5,776,161, already provides a stent with connectors where wherein the overall length of the stent is maintained during expansion:

> Globerman discloses an expandable stent having a small initial diameter, flexibility along its longitudinal axis prior to expansion and minimization of rigid local strain on the stent material by the presence of rotation joints which have minimal strain during stent expansion. *The stent is substantially the same length before and after expansion* and being flexible longitudinally when constrained, it is easy to deliver. However additional improvements in longitudinal flexibility in the crimped stent during delivery and scaffolding after delivery are still desired.

Wolinsky et al., col. 2, lines 52-62 (emphasis added).

Wolinsky et al. finds the Globerman stent to need improvement in"...longitudinal flexibility in the crimped stent during delivery and scaffolding after delivery...." See col. 2, lines 59-62.

Therefore, Wolinsky et al. actually teach away from a stent with connectors of the type disclosed by Burgermeister. Wolinsky et al. already have the features required for maintaining stent length upon expansion, and state that additional improvements are needed. Thus, it can be assumed that the Burgermeister stent connectors are insufficient to provide these

improvements. Even after *KSR*, if a reference teaches away from making such a combination, patentability is not precluded under 35 U.S.C. §103(a). See *KSR International v. Teleflex Inc.*, U.S. Supreme Court No. 04-1350, 82 USPQ2D 1385 (U.S. 2007)

Also, according to KSR, one of ordinary skill in the art must not only be able to make the predictable variation to the device, they must also be able to see the benefit in doing so. If such a benefit cannot be seen, the combination does not preclude patentability under 35 U.S.C. §103(a). See *KSR International v. Teleflex Inc.*, U.S. Supreme Court No. 04-1350 (April 30, 2007).

Because Wolinsky et al. finds connectors such as those disclosed by Burgermeister to be insufficient, one of skill in the art would not see a benefit to making such a combination.

The features employed in making this rejection are being selected from the prior art with the benefit of hindsight, using Applicant's own invention. It is well settled that "...the claimed invention must be considered as a whole, multiple cited prior art references must suggest the desirability of being combined, and the references must be viewed without the benefit of hindsight afforded by the disclosure." *In re Paulsen,* 31 USPQ2D 1671, 1676 (Fed. Cir. 1994) (string cites omitted).

As one of ordinary skill in the art would not look to the Burgermeister reference to modify the Wolinsky et al. stent because the stent already has connectors that maintain the overall stent length before and after expansion, the combination fails to render claim 1 obvious. Combining the cover of Erbel et al. with Wolinsky et al. fails to suggest a medical device with such connectors as recited in claim 1.

Claims 2, 4, 5, 7-10, 15, 34 and 35 depend from claim 1 and are not obvious over this combination for at least the reasons that claim 1 is not obvious over this combination.

Independent claim 26 and claim 27 dependent therefrom are also not obvious over this combination for at least the reasons that claim 1 is not obvious over the combination. Simply, because Burgermeister would not be combined with Wolinsky et al. for the reasons set forth herein.

Applicants respectfully request withdrawal of the rejection of claims 1, 2, 4, 5, 7-10, 15, 26-28, 34 and 35 under 35 U.S.C. 103(a) as being unpatentable over Wolinsky (USPN 6,730,116) in view of Burgermeister (USPN 6,790,227) and further in view of Erbel et al. (US Pub. 200410116998).

Wolinsky in view of Burgermeister and further in view of Erbel et al. and Barone

Claim 6 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Wolinsky in view of Burgermeister and further in view of Erbel et al., and further in view of Barone (USPN 6,613,078).

The combination of Wolinsky et al., Burgermeister and Erbel et al. has been discussed above. Claim 1 is patentable over this combination for at least the reasons provided above. One of ordinary skill in the art would simply not combine the connectors of Burgermeister with Wolinsky et al. at least because Wolinsky et al. teaches away from doing so. Therefore, combining the cover of Erbel et al. with Wolinsky et al. and Burgermeister fails to provide a case of *prima facie* obviousness, and combining two covers of Barone as asserted in the Final Office Action (page 9, paragraph no. 24) still fails to render claim 1 obvious. Claim 6 depends from claim 1 and is patentable for at least the reasons that claim 1 is patentable over Wolinsky et al., Burgermeister and Erbel et al.

Cox et al. in view of Garrison et al. and further in view of Erbel et al. and Barone

Cox et al., Garrison et al. and Erbel et al. have been discussed above. Claim 1 is patentable over this combination for the reasons given above. The combination fails to suggest the stent of claim 1. Cox et al., Garrison et al. and Erbel et al., all fail to disclose a stent with a special strut as recited in Applicant's claim 1. Combining the two stent covers of Barone, as asserted in the Office Action, with Cox et al., Garrison et al. and Erbel et al. fails to render claim 1 patentable because the combination fails to provide a most notable feature of claim 1, i.e. the special strut as recited therein. Claim 6 is patentable over this combination for at least the reasons that claim 1 is patentable over this combination.

Applicants respectfully request withdrawal of the rejection of claim 6 under 35 U.S.C. §103(a) as being unpatentable over Wolinsky et al. in view of Burgermeister and further in view of Erbel et al.; and Cox et al. in view of Garrison et al. and further in view of Erbel et al. as applied to claim 1 above, and further in view of Barone (USPN 6,613,078).

Cox et al. in view of Garrison et al., and
further in view of Erbel et al. and admitted prior art

Claims 13 and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Cox in view of Garrison and further in view of Erbel as applied to claim 1 above, and further in view of admitted prior art (admission).

The combination of Cox et al., Garrison et al. and Erbel et al. fails to provide all of the requisite features of claim 1, namely, the special strut located within a single serpentine band of a stent between a peak and a trough. This element is simply not found in this combination of references and therefore, a *prima facie* case of obviousness has not been established.

Combining plating, painting, pressing, sawing or welding or any other means known in the art with this combination of references still fails to provide the special strut recited in claim 1. Therefore, claims 13 and 14 are patentable over this combination for at least the reasons that claim 1 is patentable over this combination.

Wolinsky et al. in view of Burgermeister and further in view of Erbel et al., as applied to claim 1, above, and further in view of admitted prior art (admission)

Claim 1 is also patentable over Wolinsky et al. in view of Burgermeister and further in view of Erbel et al. for at least the reasons as discussed above. One of ordinary skill in the art would simply not modify the Wolinsky et al. stent with the features, e.g. connectors, of Burgermeister, because the Wolinsky et al. already has connectors that maintain overall stent length upon expansion.

Combining plating, painting, pressing, sawing or welding or any other means known in the art with this combination of references still fails to provide the special strut recited in claim 1 and claims 13 and 14 are patentable over this combination for at least the reasons that claim 1 is patentable over this combination.

Applicants respectfully request withdrawal of the rejection of claims 13 and 14 under 35 U.S.C. §103(a) as being unpatentable over Cox et al. in view of Garrison et al. and further in view of Erbel et al.; and Wolinsky et al. in view of Burgermeister and further in view of Erbel et al. as applied to claim 1 above, and further in view of admitted prior art (admission).

CONCLUSION

Claims 1, 2, 4-10, 13-18, 22-28, 34 and 35 are pending in the application. Applicants have addressed each of the issues presented in the Office Action. Based on the foregoing, Applicants respectfully request reconsideration and an early allowance of the claims as presented. Should any issues remain, the attorney of record may be reached at (952)563-3011 to expedite prosecution of this application.

Respectfully submitted,

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